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PATENT COOPERATION TREATY

PCT

REC'D 11 JAN 2005

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

|   |  |  |
|---|--|--|
| Applicant's or agent's file reference<br>65455WOP00   | <b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416). |  |
| International Application No.<br><b>PCT/AU2003/001176</b>   | International Filing Date<br>(day/month/year)<br>8 September 2003  | Priority Date (day/month/year)<br>6 September 2002 |
| International Patent Classification (IPC) or national classification and IPC<br><b>Int. Cl.<sup>7</sup> C12N 1/20</b> |  |  |
| Applicant<br><b>VRI BIOMEDICAL LTD et al</b>  |  |  |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

|   |  |
|---|--|
| Date of submission of the demand<br>6 April 2004  | Date of completion of the report<br>21 December 2004                               |
| Name and mailing address of the IPEA/AU<br>AUSTRALIAN PATENT OFFICE<br>PO BOX 200, WODEN ACT 2606, AUSTRALIA<br>E-mail address: pct@ipaaustralia.gov.au<br>Facsimile No. (02) 6285 3929 | Authorized Officer<br><br><b>CHRISTOPHER LUTON</b><br>Telephone No. (02) 6283 2256 |

**I. Basis of the report****1. With regard to the elements of the international application:\***

- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,  
pages , filed with the demand,  
pages , received on with the letter of
- ☐ the claims, pages , as originally filed,  
pages ; as amended (together with any statement) under Article 19,  
pages , filed with the demand,  
pages , received on with the letter of
- ☐ the drawings, pages , as originally filed,  
pages , filed with the demand,  
pages , received on with the letter of
- ☐ the sequence listing part of the description:  
pages , as originally filed  
pages , filed with the demand  
pages , received on with the letter of

**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

**3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:**

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

**4. ☐ The amendments have resulted in the cancellation of:**

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

**5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\***

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

|                               |             |     |
|-------------------------------|-------------|-----|
| Novelty (N)                   | Claims 1-32 | YES |
|                               | Claims      | NO  |
| Inventive step (IS)           | Claims 1-32 | YES |
|                               | Claims      | NO  |
| Industrial applicability (IA) | Claims 1-32 | YES |
|                               | Claims      | NO  |

**2. Citations and explanations (Rule 70.7)**

The following documents identified in the International Search Report have been considered for the purposes of this report:

D1 – Plant and Conway  
D2 – Heinemann et al.  
D3 – Blomberg et al.  
D4 – WO 2002/034273

The present invention relates to a variant of *Lactobacillus fermentum* having the characteristics as described in claim 1 and uses thereof.

**NOVELTY (N) and INVENTIVE STEP (IS) Claims 1-32**

D1 discloses a strain of *L. fermentum* which adheres to Peyer's Patches at greater than log 5 cfu (see abstract and page 321, 2<sup>nd</sup> column, line 29). However, D1 does not disclose or suggest *L. fermentum* which ferments all of ribose, galactose, glucose, fructose, mannose, maltose, lactose, melibiose, sucrose, trehalose, raffinose, L-arabinose and mannitol. Therefore, the claims are novel and involve an inventive step in light of D1.

D2 discloses the purification and characterisation of a surface-binding protein from *L. fermentum*. However, D2 does not disclose or suggest an *L. fermentum* variant having all of the features of claim 1. Therefore, the claims are novel and involve an inventive step in light of D2.

D3 teaches that *L. fermentum* produces a component that interacts with mucus components and inhibits adhesion of *E. coli* K88 fimbriae. However, D3 does not disclose or suggest an *L. fermentum* variant having all of the features of claim 1. Therefore, the claims are novel and involve an inventive step in light of D3.

D4 discloses the administration of *L. fermentum* to induce a Th1-type response.. However, D4 does not disclose or suggest that the *L. fermentum* has all of the features of the *L. fermentum* of claim 1. Therefore, the claims are novel and involve an inventive step in light of D4.

**VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Various claims define "components" of *L. fermentum* and their use. The scope of the term "component" is indeterminate. It may include simple, known, chemical substances within its scope. Therefore, many of the claims are, prima facie, not novel. Moreover, many of the claims do not define the subject matter for which protection is sought in terms of the technical features of the invention (Rule 6.3(a)).

The specification is not enabling for *L. fermentum* variants beyond the specifically deposited example (VRI003). The specification fails to provide any means, beyond the deposited strain, for performing the invention.